UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 10-3933CAS (FFMx)	Date	June 13, 2011
Title	GORDIAN MEDICAL, INC. v. KATHLEEN SEBELIUS, ETC.		

Present: The Honorable	CHRISTINA A. SNYDER	
ISABEL MARTINEZ/ CATHERINE JEANG	LAURA ELIAS	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.

Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Lesley Reynolds	Russell Chittenden

Proceedings: **PLAINTIFF'S MOTION FOR LEAVE TO SERVE DISCOVERY** (filed 03/25/11)

SCHEDULING CONFERENCE

I. INTRODUCTION

On May 25, 2010, plaintiff Gordian Medical, Inc. filed suit against Kathleen Sebelius, in her official capacity as Secretary of Department of Health and Human Services ("defendant" or "Secretary"). Plaintiff filed a first amended complaint ("FAC") on January 14, 2011. Plaintiff seeks judicial review of a final decision by the Secretary, through the Medicare Appeal Council, to deny plaintiff's claims for Medicare reimbursement for composite dressings plaintiff provides to Medicare beneficiaries.

On March 25, 2011, plaintiff filed the instant motion for leave to serve discovery on the Secretary. On May 23, 2011, the Secretary filed an opposition. Plaintiff replied on May 27, 2011. After carefully considering the arguments set forth by both parties, the Court finds and concludes as follows.

II. BACKGROUND

Plaintiff is a Medicare enrolled supplier of wound care supplies, including non-bordered composite dressings. FAC ¶¶ 7–8. Plaintiff's dressings are eligible for federal reimbursement under Part B of the Medicare Act, 42 U.S.C. §§ 1395j–1395w-4. FAC ¶ 11. To obtain reimbursement, Medicare suppliers submit claims to a Durable Medical Equipment Medicare Administrative Contractor ("DME-MAC"), that are agents of the

Centers for Medicare & Medicaid Services ("CMS"). FAC ¶ 15. The United States is divided into four geographic jurisdictions ("A" through "D"), each of which is assigned a DME-MAC. Id. During the relevant time period, the Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC") – a CMS agent and contractor – offered guidance to Medicare suppliers on the proper billing codes for covered supplies. FAC ¶¶ 19–20. In December 2004 and April 2006, SADMERC assigned billing codes to plaintiff's composite dressings, qualifying those dressings for Medicare reimbursement. FAC ¶ 25.

Beginning in 2004, DME-MACs began denying a high percentage of plaintiff's reimbursement claims based on a purported lack of medical necessity. FAC ¶ 27. Almost all of the DME-MACs denials were reversed on appeal by Administrative Law Judges ("ALJs"). Id. Plaintiff alleges that the DME-MACs, faced with the prospect of continuing reversals in the administrative appeals process, devised a strategy that would allow them to deny plaintiff's claims while shielding their decisions from administrative review. FAC ¶ 29. Plaintiff alleges that Medicare program contractors published a "Policy Article" unilaterally changing the definition of "composite dressings" to require, without medical justification, that the dressings have a physical adhesive border. FAC ¶¶ 30–33. Thereafter, Medicare contractors invalidated the billing codes that applied to plaintiff's dressings, and stopped reimbursing claims under the old codes in a manner that precluded further administrative review. FAC ¶¶ 34–54. Plaintiff alleges that these changes were contrary to established procedures for revising definitions and changing billing codes. FAC ¶¶ 30–49. As a result, plaintiff claims to have been denied reimbursement totaling $4,928,189.95. FAC ¶ 50.

In response to these actions, on February 25, 2008, plaintiff filed suit against the Secretary in the United States District Court for the District of Columbia in American Medical Technologies v. Johnson, CV No. 08-00319 (JDB).[1] FAC ¶ 55. On February 25, 2009, the court dismissed plaintiff's lawsuit for lack of subject matter jurisdiction due to the Medicare statute's jurisdictional exclusivity and exhaustion requirements. See Am. Med. Techs. v. Johnson, 598 F. Supp. 2d 78, 83 (D.D.C. 2009). Relying on the Secretary's suggestion, the court determined that plaintiff could have obtained

[1] Plaintiff was then referred to by the name of its predecessor, American Medical Technologies, Inc. FAC ¶ 7.

administrative review under 42 C.F.R. § 405.924(b)(12) by "submitt[ing] claims for reimbursement using the new codes rather than the old ones."[2] Id. at 82. The court held that 42 C.F.R. § 405.926(c), which precludes appeals of "[a]ny issue regarding the computations of the payment amount of program reimbursement of general applicability . . . such as the establishment of a fee schedule," would not bar judicial review because plaintiff would be challenging the approach the Medicare contractors used in invalidating the old codes and issuing the new ones. Id. at 83.

Thereafter, plaintiff availed itself of the administrative appeals process and sought administrative review of its claims for non-bordered composite dressings by filing certain claims using the new codes, and additional claims using the original codes. FAC ¶ 59. Plaintiff alleges that its entire universe of claims for composite dressings are at various stages of administrative appeal. Id. The claims for non-bordered composite dressings that are the subject of the Secretary's final decision and that are the subject of this case were filed using the original codes for non-bordered composite dressings. FAC ¶ 60.

Reimbursement for the claims at issue was originally denied by a Medicare contractor. Id. Plaintiff requested reconsideration of the denials by the Qualified Independent Contractor ("QIC"). FAC ¶ 61. The QIC also denied Medicare coverage of these claims. Id. Plaintiff then sought review by an ALJ, who ultimately concluded that the claims were not covered by Medicare. FAC ¶ 62. The ALJ did not address the validity, reasonableness or enforceability of the revised definition of "composite dressing" or the changed billing codes. Id. Plaintiff appealed to the final level in the administrative appeals process by seeking review in the Medicare Appeals Council ("MAC"). FAC ¶ 63. The MAC held that "[n]either an ALJ nor the Council have the authority to review . . . the [Medicare contractors'] invalidation of [billing] codes, or any CMS action or inaction with respect to coding issues." Administrative Record ("AR") 6. Accordingly, the MAC held that plaintiff's claims for non-bordered composite dressings billed under the original codes were not covered items under Medicare. AR 7.

Plaintiff then filed this suit seeking relief under the Medicare statute and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551 et seq. and 701 et seq.

[2] 42 C.F.R. § 405.924(b)(12) provides that any issue "having a present or potential effect on the amount of benefits to be paid" may be appealed.

III. DISCUSSION

Plaintiff seeks to serve discovery on the Secretary, including requests for admissions, requests for the production of documents, and interrogatories. See Mot., Exh. 2. Generally, judicial review of agency action is confined to review of the administrative record. Animal Defense Council v. Hodel, 840 F.2d 1432, 1436 (9th Cir. 1988); see also Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. USDA, 499 F.3d 1108, 1117 (" It is an established rule that 'the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.'") (quoting Camp v. Pitts, 411 U.S. 138, 142 (1973)). The Ninth Circuit has carved out four "narrow" exceptions for extra-record evidence:

> (1) if admission is necessary to determine whether the agency has considered all relevant factors and has explained its decision, (2) if the agency has relied on documents not in the record, (3) when supplementing the record is necessary to explain technical terms or complex subject matter, or (4) when plaintiffs make a showing of agency bad faith.

Ranchers Cattlemen, 499 F.3d at 1117. The parties agree that the same test applies for discovery as for supplementation of the record. See Protect Lake Pleasant, LLC v. Johnson, No. CIV 07-0454-PHX-RCB, 2008 U.S. Dist. LEXIS 118275, at *9 (D. Ariz. May 5, 2008). Here, plaintiff argues that discovery is necessary to permit effective judicial review and because the Secretary's actions show that she acted in bad faith in an effort to shield her actions from administrative review. Mot. at 11–22. The Court addresses each argument in turn.

A. Permitting Effective Judicial Review

Plaintiff argues that discovery will help the Court understand why Medicare contractors changed the definition of "composite dressing," and invalidated the relevant codes, without following the established CMS procedures. Mot. at 11. Plaintiff asserts that under CMS guidelines and federal law, the Secretary is required to provide an opportunity for public comment on any coding modifications through the Healthcare Common Procedure Coding System ("HCPCS") Workgroup. Id. at 11–12. Moreover, according to plaintiff, the HCPCS Workgroup is the entity responsible for making the

final decisions pertaining to revisions to the codes. Id. at 12. Plaintiff contends that the Medicare contractors bypassed the mandatory HCPCS Workgroup process, and unilaterally revised the definition of "composite dressing" and changed the relevant codes without explanation. Id. at 12–14. As such, plaintiff argues that effective judicial review will be frustrated unless the Court can ascertain why the Medicare contractors chose not to follow the established procedures set forth by CMS. Id. at 14–15 (citing Camp, 411 U.S. at 142 (when "failure to explain administrative action" will "frustrate effective judicial review," the court may "obtain from the agency, either through affidavits or testimony, such additional explanations of the reasons for the agency decision as may prove necessary")).

In support of its argument that the Secretary failed to explain her decision, plaintiff points to certain pieces of evidence the agency could have or should have considered. Mot. at 16–17. For example, when the agency changed the codes, plaintiff contacted CMS' Coverage and Analysis Group ("CAG") for clarification of the agency's action. AR 197–198. Although the Secretary acknowledges that the CAG discussed the invalidation of the codes, plaintiff argues that there is no information about these proceedings in the administrative record. Mot. at 16. Similarly, plaintiff maintains that expert testimony in the administrative record suggests that there is no medical justification for the change in the definition of "composite dressing." Id. (citing FAC. Exh. 2). Plaintiff contends that discovery is necessary to better understand what medical evidence the agency reviewed, and should have reviewed, prior to revising the definition. Id. at 16–17.

The Secretary responds that plaintiff has failed to demonstrate that the record is so inadequate that judicial review would be effectively frustrated. Opp'n at 9 (citing Animal Defense Council, 840 F.2d at 1436). The Secretary argues that discovery would be especially inappropriate because the administrative appeals process afforded plaintiff the right to introduce evidence and thereby contribute to the record to be reviewed by this Court. Id. (citing 42 C.F.R. §§ 405.946, 405.966, 405.1018, 405.1122). Instead, the Secretary points out, plaintiff chose to have the ALJ decide the case based solely on the documentary evidence. Id. at 10 (citing AR 220).

The Secretary further argues that discovery is not necessary to determine whether the agency has considered all relevant factors and has explained the final decision because the MAC based its denial of plaintiff's appeal on the grounds that the codes for

plaintiff's composite dressings were not covered under CMS' July 2007 HCPCS Quarterly Update. Id. at 11–12 (citing AR 7). Accordingly, the Secretary contends that the record contains "everything that was before the agency pertaining to the merits of the decision." Id. at 12 (quoting Animal Defense Council, 840 F.2d at 1436).[3]

Plaintiff replies that the Secretary misconstrues the nature of its case. Reply at 2. Plaintiff argues that, contrary to the Secretary's characterization, its case is not about the relevant dates of service, but instead whether the agency followed the required processes when it invalidated the codes for composite dressings. Id. Plaintiff asserts that when it attempted to raise this issue in the administrative process, the Secretary claimed to have no jurisdiction to review the issue. Id. at 3–4. Plaintiff further replies that because the administrative review process claimed a lack of jurisdiction over these issues, there was no way for plaintiff to develop the administrative record. Id. at 5. Plaintiff further argues that it could not augment the administrative record with discovery in the Secretary's possession because discovery in Medicare appeals cases is extremely limited. Id. (citing 42 U.S.C. § 405.1037). Thus, plaintiff maintains that the record must be developed through discovery to permit effective judicial review. Id. at 4–5.

The Court finds that, at this stage, discovery is not necessary to determine whether the Secretary has adequately explained her decision. The MAC claimed that it lacked jurisdiction to address plaintiff's challenge to the process that the agency followed when it changed the definition of "composite dressings" and revised the relevant codes. See AR 6–7. The Court believes that the MAC adequately explained its decision on this issue, and the Court can review the MAC's determination without permitting discovery. As such, plaintiff has failed to carry its burden of demonstrating that effective judicial review will be frustrated unless the Court permits discovery.[4] See Californians for

[3] The Secretary argues that the discovery sought by plaintiff is irrelevant for the same reason. Opp'n at 14–15.

[4] Plaintiff further contends that discovery is appropriate because it will help guide the Court in technical matters, including the medical necessity of its composite dressings. Mot. at 17–18. The Court disagrees. Supplementation of the record is not necessary to explain technical terms or complex subject matter because plaintiff's claims were not denied based on a lack of medical necessity.

Alternatives to Toxics v. U.S. Fish & Wildlife Serv., No. 2:10-cv-1477 FCD CMK, 2011 WL 838957, at *3 (E.D. Cal. Mar. 3, 2011) ("A plaintiff bears the burden of demonstrating that the administrative record is so inadequate that judicial review would be effectively frustrated.") (internal quotation marks omitted).

B. Bad Faith

The Ninth Circuit has held that "normally there must be a strong showing of bad faith or improper behavior before the court may inquire into the thought processes of administrative decisionmakers." Animal Defense Council, 840 F.2d at 1437 (quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420 (1971), overruled on other grounds by Califano v. Sanders, 430 U.S. 99 (1977)). Plaintiff argues that it has made a sufficient showing that the Secretary acted in bad faith by devising a scheme to ensure denials of plaintiff's claims, and then shielding those denials from administrative review. Mot. at 19. The fact that the Medicare contractors unilaterally changed the definition of "composite dressings" and redefined the HCPCS codes is strong evidence that the Secretary acted in bad faith, plaintiff argues. Id. at 19–20. Plaintiff asserts that the Medicare contractors made these changes by way of a "Policy Article" to avoid any effective administrative review of these claims and to protect DME-MACs from further reversals. Id. at 20. Plaintiff further argues that the Medicare contractors' lack of scientific basis for making these changes also supports its showing of bad faith. Id.[5]

The Court is not convinced that extra-record discovery is justified based on plaintiff's claim of bad faith. Although plaintiff points to certain anomalies in the administrative process, the allegation that the Secretary nefariously devised a scheme to ensure denials of plaintiff's claims is unsubstantiated. Accordingly, plaintiff has failed to make such a "strong showing" of bad faith to allow for extra-record discovery in this case. See Animal Defense Council, 840 F.2d at 1437. Furthermore, to the extent

[5] To explore its allegation that the Secretary acted in bad faith, plaintiff seeks discussions about how DME-MACs responded to being reversed by the ALJs. Mot. at 20–21. Plaintiff further seeks documents relating to the Medicare contractors revisions to the definition of "composite dressings," the changing of the HCPCS codes, and communications between Medicare contractors and their medical directors regarding the codes. Id. at 21.

plaintiff relies on the Ninth Circuit's decision in Public Power Council for the proposition that discovery is permissible to explain whether the Secretary's actions were in bad faith, so long as its arguments are not "insubstantial or frivolous," plaintiff's argument is unavailing. See Mot. at 21–22 (quoting Public Power Council v. Johnson, 674 F.2d 791, 795 (9th Cir. 1982)). Courts in this circuit have recognized that Public Power Council is "somewhat of an anomaly," and that "simply raising the *specter* of improper motive and bad faith . . . does not establish the requisite strong showing of bad faith or improper behavior necessary to justify extra-record discovery." Protect Lake Pleasant, 2008 U.S. Dist. LEXIS 118275, at *23–25 (internal quotation marks omitted) (emphasis in original).

IV. CONCLUSION

In accordance with the foregoing, the Court hereby DENIES plaintiff's motion for leave to serve discovery.

IT IS SO ORDERED.

: 10

Initials of Preparer IM